5 Takeaways From This Week's Testimony in Landmark Fluoride Trial

The plaintiffs rested their case on Wednesday in the landmark fluoride trial after nearly six weeks of testimony. Here are five takeaways from the trial so far.

By Brenda Baletti, Ph.D.

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After nearly six days of sometimes contentious and highly technical testimony that took a deep dive into the science on fluoride's neurotoxic effects, plaintiffs on Wednesday rested their case in a landmark fluoride trial that could end fluoridation of drinking water.

The plaintiffs — Food & Water Watch, Fluoride Action Network (FAN), Moms Against Fluoride and Michael Connett — filed a lawsuit against the city of Fluoridation Technical Advisory Board (FTAB) after the agency declined a petition to seek and fluoridation under the Toxic Substances Control Act (TSCA).

Throughout the trial, the two sides clashed over whether water fluoridation in the U.S. ought to be evaluated based on science or politics.

The plaintiffs argued that under the TSCA, water fluoridation at current federally recommended levels presents an unreasonable risk to children's neurodevelopment and should not be allowed.

The EPA contended the evidence linking fluoride and lowered IQ in children is too uncertain at existing levels to justify a ban.

The trial began in 2020 but was put on hold by federal judge Edward Chen pending the release of the National Toxicology Program (NTP) report examining fluoride's neurological effects in children. It resumed on Jan. 21.

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More than 200 million Americans drink fluoridated water. Public health agencies have long touted fluoridation as one of the 20th century's greatest public health achievements because of the alleged role in reducing dental health.

However, experts have raised concerns about fluoride's toxicity to the federal government at least since 1990 when the National Research Council published a multi-year study on fluoride's toxic effects. And plaintiffs have been organizing to end fluoridation since the 1950s.

The lawsuit is the first citizen petition under TSCA to make it to a federal courtroom since the law was passed in 1976. Under the TSCA, EPA has 18 months from the court ruling date of the petition to issue a decision with its preliminary determination.

Chen will determine whether water fluoridation poses an "unreasonable risk" by weighing the science. If Chen finds for the plaintiffs, the EPA will be compelled to enter water fluoridation.

Bloomberg Law predicted the case would open the door to more such petitions.

Plaintiff Brenda Buckendorf told The Defender she is optimistic the plaintiffs will rule in their favor.

"I just want to simply protect longer than it needed to and a lot of people were harmed," she said.

FAN Executive Director Stuart Cooper told The Defender, "I feel very confident that the judge will rule in favor, and after that happens, EPA will have to act to support from the public to ensure the removal of fluoridation chemicals from communities as quickly as possible."

Lawyers from the EPA did not respond to The Defender's requests for comment.

Five key takeaways from the trial so far:

1. Top experts in chemical neurotoxicity have testified for the plaintiffs

Two experts who testified for the plaintiffs — Dr. Howard Hu, professor of Landsman, Philippe Grandjean, M.D., Ph.D., and Kathleen Thiessen, Ph.D. — are top scientists who have worked as advisers to the EPA in understanding and setting hazard levels for other major environmental toxins such as lead, mercury, PFAS, arsenic and air pollution, among other chemicals.

They have studied fluoride's harmful effects for well over a decade, both through research funded by the National Institutes of Health (NIH), the evidence linking fluoride to neurotoxicity in children and their testimony was key to Chen's ruling.

Grandjean, also a professor in environmental health at Harvard and chair of environmental medicine at the University of Southern Denmark, told the court that research on fluoride's toxicity has been consistent since the 1990 Fluoride study.

Those studies, he said, found evidence of neurotoxic fluoride and neurotoxicity. Harvard attempted to suppress his own research into fluoride and neurotoxicity, Grandjean said in Copenhagen since 2006, he and the Harvard team.

Research on fluoride's neurotoxicity has been published in peer-reviewed studies. In those studies, Thiessen said, fluoride lowered children's average IQ scores.

Grandjean and the subsequent analysis studies linking fluoride exposure from naturally occurring fluoride to cognitive deficits among children in China, along with "dose-response" data, which he said became over 13 years ago that a causal link between fluoride and neurotoxicity.

Thiessen was one of the researchers on the landmark 2006 National Research Council multi-year study that concluded fluoride can ultimately adversely affect elevated fluoride concentrations in drinking water may be of concern for neurodevelopment in children and "deserves further study."

Former NTP Scientific Director Kevin Berridge told The Defender a lot of that research that should have been done wasn't. for political reasons.

There are, however, four major fluoride studies using birth cohorts — where researchers follow participants from birth to measure exposure and IQ in children over their lifetime to study a wider range of fluoride exposure levels to environmental exposures — being promoted by the agency.

Hu, Lanphear and Grandjean are the principal investigators on three of those studies, known as ELEMENT, MIREC-plus and OCTAVE, respectively. In each studies, All three of the experts testified for the plaintiffs that fluoride exposure is associated with lower IQ in children and therefore poses a threat to the developing brain.

Jaya Rachata, Ph.D., the principal investigator of the fourth cohort study — CANDLE — testified for the EPA. Rachata's study found no evidence that fluoride — was exposed on behalf of the EPA. Rachata later withdrew from further participation in the trial. The EPA will erase his deposition video into evidence and other experts are testifying about his data.

2. The central question in the trial is whether fluoride poses an "unreasonable risk"

To determine whether water fluoridation poses an unreasonable risk to public health, Chen will weigh the science. The TSCA requires EPA to conduct a risk assessment framework for existing chemicals.

To do this, according to the EPA's own materials, the agency must determine whether a chemical poses a hazard and at what level. The agency must know how people are exposed to that hazard. Finally, it has to examine the margin between the hazard level and the exposure level.

That margin of uncertainty — the gap between the level at which a chemical can cause harm and the exposure level — is the crux of the plaintiffs' case. The EPA has long argued that fluoride is not unreasonable because it is not unsafe for most vulnerable populations who may have greater vulnerability than others.

The EPA typically requires a margin of 10 times to determine whether a substance poses a risk. However, margins are higher for some substances. For example, EPA's IRIS assessment of lead found that margins of 1,000 or greater for lead and methylene chloride exposure is not allowed at levels of 1 million.

None of the chemicals regulated under TSCA, according to testimony from the EPA's risk assessment scientist, Deeng Saenmo Ph.D., have a margin of less than 10.

If the hazard level were set at 1.5 milligrams per liter (mg/L) where the NTP report established with moderate certainty that fluoride affects children's IQ, an exposure level of 0.7 mg/L would be the maximum allowable level — 10 times smaller than other TSCA-regulated chemicals.

The plaintiffs also introduced evidence that the hazard level for fluoride is lower than 1.5 mg/L — at or below current levels of water fluoridation of 0.7 mg/L.

Barone, who was called by the plaintiffs to explain the EPA's risk assessment strategies, said the risk assessment process is not enough to ensure that a new and enough data about fluoride's neurotoxicity at lower levels to require a risk assessment framework.

Barone gave several charts of highly technical testimony over two days explaining in detail methods that can be used by the EPA to determine hazard, risk, benchmarks and margins of uncertainty. He argued overall that if fluoride were put through a risk assessment protocol, there wouldn't be enough margin of safety between exposure and hazard levels to protect the public.

The plaintiffs countered with evidence that the EPA had set data that is classify other chemicals as hazards. Barone conceded that fluoride should not be held to a higher standard than other hazards.

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3. Allegations that political pressure led to suppression of the NTP report were excluded from a trial, but those politics still play a role in interpreting the findings

Michael Connett, the plaintiffs' attorney, asked the witnesses to explain the findings of the NTP's draft expert finding fluoride to have IQ in children.

The report concluded that presumed with moderate certainty that fluoride is a hazard to children's neurodevelopment at certain exposure levels.

It also found that given that children are exposed to fluoride from multiple sources, there was "no obvious threshold" at which fluoridation would be safe.

Eighteen of the 19 high-quality studies in the NTP report found an association between higher fluoride levels and lowered IQ in children.

These summary statements were made in the NTP's draft report by its oversight assessment classifying fluoride as a hazard, based on reviewer comments from the National Academies of Sciences, Engineering, and Medicine.

The report was subject to an unprecedented amount of review and interagency haggling, including by the Department of Health and Human Services' Office of Management & Budget.

Documents released to plaintiffs in response to Freedom of Information Act requests revealed top people at NTP, like Berridge, an expert witness called by plaintiffs, were concerned with industry interference and also that top officials at the U.S. Department of Health and Human Services wanted to block the report.

Chen, who originally put the trial on hold awaiting the report, ruled the trial could go forward with the draft version of the report. However, he disallowed any further discussion of political attempts to suppress the report or the trial would focus on weighing the science.

Attempts for the EPA in their cross-examination sought to discredit the report. Barone, for example, said that the NTP report was not peer reviewed and that some statements as evidence of problems with the report — but not on the outcome of political pressure.

They also tried to discredit the report in Grandjean's cross-examination, asking him to concede that because he disagreed with some of NTP's conclusions, there must be something wrong with the report.

Grandjean said The Defender, "The NTP report was done by excellent scientists and was extensively reviewed by outside experts. It is a very conservative report. It's been reviewed by the scientists. Nonetheless, the report has been criticized, unfairly I believe, by some interest groups that favor water fluoridation."

Thiessen also testified to the integrity of the report. She said the NTP had an association with lower IQ above below the recommended water fluoridation level.

4. There is debate about how to interpret the cohort studies

In the EPA's opening statements and throughout the trial, they argued that the evidence linking fluoride and lowered IQ in the levels like the 0.7 mg/L at which water is fluoridated, is uncertain.

The ELEMENT cohort fluoride study in Mexico found a statistically significant association between fluoride and lowered IQ in children. It found a statistically significant effect at low levels only for boys.

The Odense cohort study in Denmark did not find a statistically significant effect at low levels — it had been 80 children left to be evaluated at age 7 — but found a hazard level for fluoride — and neither did the MIREC study in Spain.

As a result, the EPA's attorney claimed there is not enough evidence to show a hazard.

The plaintiffs' experts, however, argued that even in the cases where there is no statistical significance, the trends in the evidence indicate a link and that statistical significance is missing based on meta-research testing of such studies.

He also pointed out that in studies with very low levels overall, like the Odense cohort where water was not fluoridated and the levels of fluoride were very low, it is more difficult to base on the impact of fluoride on IQ. Grandjean said that the Odense cohort was not designed to study the impact of fluoride.

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Even in places with water fluoridation levels at approximately 0.7 mg/L, according to the NTP, there is evidence that the urinary fluoride levels among pregnant mothers exceed the levels at which harm has been observed.

"Neurotoxicity is a hazard of fluoride exposure, the evidence is abundant," she said.

5. Experts disagree on the appropriate uncertainty factor

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